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10/004,642	12/04/2001	Adam Kois	10624-049-999	6698

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EXAMINER	
FORD, JOHN M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 10/004642	Applicant(s) Kois et al
	Examiner J.M. Ford	Group Art Unit 1624

—The MAILING DATE of this communication appears on th cover sheet beneath th correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ R sponsive to communication(s) filed on 2-28-02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1 — 38 is/are pending in the application.

Of the above claim(s) 12 — 37 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 — 11 and 38 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Stat ment(s), PTO-1449, Paper No(s). _____

☐ Intervi w Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Oth r _____

Office Action Summary

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph, as a result of the use of aryl and heteroaryl and heterocycle, alone or in a combined term.

Judge Smith found multiple, different, definitions for aryl in In re Sus, 134 USPQ 301, and listed some of the different definitions for aryl in the footnotes of that case. Therefore, applicants need to tell us what they intend by aryl.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph, Clarification is requested.

Heteroaryl is entirely inadequate. Where are the heteroatoms in the ring? How many hetero atoms are present in the ring. Applicants are placing specific conception with the reader. Not a fair burden in return for applicants getting a 17/20 year monopoly on compounds, not yet made. Adjacent O/S; O/O or S/S combinations have not been made, as they are notoriously unstable. What is the source of the starting materials? These are compound claims that carry with it the right to exclude others. Applicants should not be permitted to pre-empt others from future endeavors, when they, the public, finally do make the compounds, included in the huge language applicants suggest.

Claim 1 is, therefore, also rejected under 35 U.S.C. 112, 1st paragraph, as the specification does not contain adequate representative exemplification for the breadth claimed.

The USPTO only recognizes: C, N, O, S, Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heteroary/,

Heterocyclic is not just a substituent; it is whole body of art, larger than the nucleus claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

What the heteroaryl is, may often control the classification and search of the molecule.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.

Conception of what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Cp. vs Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basics reasons for rejecting claims under 35 U.S.C. 12; first is that language used is not precise enough to provide a clear-cut indication of scope of subject matter embraced by claim;

this ground finds it's basis in second paragraph of section 112; second is that language is so broad that it causes claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is so broad that it causes the claim to potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 12, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

Specific conception of what the intended heteroaryl ring, may be, should not be left to the reader. In regard to

R5

R6

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1,3,4, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, in reading the indication of heterocyclic applied by applicant, has no idea where the hetero atoms are in this unknown ring,.

What are the hetero atoms? What size is the ring?

The heteroaryl term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

It becomes necessary for applicants to indicate in the claims what they mean by heteroaryl. Heteroaryl, means many different things to different people. Some definition of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O does not consider those heterocyclic, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming and support in the specification for the variables sought.

This rests specific conception with the reader.

What exactly is intended, and where is that supported in the specification.? Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quire large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is a, pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicant's breadth of heteroaryl produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they demonstrated as a specific fact.

The heteroaryl expression in claim 1 et seq., is not acceptable, as it does not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, United Carbon Co. Vs. Binney & Smith Co., 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of claims held to this standard in Lockhead Aircraft Corp. Vs. United States, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

In regard to "aryl, note.

In re Sus, 134 USPQ 301, indicates that there are multiple different definitions of aryl. Note the footnotes in the In Sus, above. Therefore, it becomes necessary for applicants to indicate what they mean by aryl. Similarly, heterocyclic has different definitions, as noted above, and requires clarification by applicants as to what they intend it to mean.

Note the Proviso at the end of claims 4 and claim 6. Closely related compounds would be obvious from the compounds removed by exception; In re Nomiya et al., 184 U.S.P.Q. 607. Applicants claim the next adjacent compound by simple substitution to the one removed. This type of close claiming cannot be allowed.

These are prima facie obvious compounds from the compounds removed.

The next adjacent compound would be structurally obvious. See, In re Dillon, 919 F.2d at 696, 16 U.S.P.Q. 2d at 1904. See also Deuel, 51 F.3d at 1558, 34 U.S.P.Q. 2d at 1214 ("Structural relationships may provide the requisite motivation or suggestion to modify one compound to obtain another compounds. For example, one compound may suggest its homologs, because homologs often have similar properties, and, therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

Others structural similarities have been found to support a prima facie case of obviousness. E.g., In re May, 574 F.2d 1082, 1093-95, 197 U.S.P.Q. 601, 610-11 (CCPA 1978) (stereo isomer); In re Wilder, 563 F.2d 457, 563 F.2d 457, 460, 195 U.S.P.Q. 426, 429 (CCPA 197) (adjacent homologs and structural isomers); In re Hoch, 428 F.2d 1341, 1344, 166 U.S.P.Q. 406, 409 (CCPA 1970) (acid and ethyl ester); In re Druey, 319 F.2d 237, 240, 138 U.S.P.Q. 38, 41 (CCPA 1963) (omission of methyl group from pyrazole ring).

A compound need not be a homology or isomer of a prior art compound in order to be susceptible to a rejection based on structural obviousness.

Thus, a difluorinated compound was held unpatentable over the prior art di chloro compound on the basis of analogical reasoning. Ex parte Wiseman (POBA 1953) 98 U.S.P.Q. 277.

In re Nomiya, 184 USPQ 607, provides that it is reasonable to conclude that the compounds removed by exception are known.

We reject on compounds, not citations. It is, therefore, reasonable to reject the presently claimed compounds as obvious (35 U.S.C. 103) from the compounds removed by exception, whether we know the citation of the compounds or not.

Therefore, claims 4 and 6 are rejected as obvious (35 U.S.C. 103) from the compounds removed by exception.

Claims 2, 4, 6, and 7 are rejected for the reasons claim 1 was rejected. What is the heterocycle? What is the aryl?

Claims 3, 5, 8, 9, 10 and 11 and 38 are rejected as they are dependent on a rejected claim, not for reasons within themselves.

Claim 12 is not allowable for the reasons noted in regard to claim 1.

Further "a condition responsive to IKK-2 inhibition" is not a real world disease, and does not meet the Utility guidelines. Such a run on sentence: any condition responsive to IKK-2 inhibition, is obviously not one thing. See claims 13--33.

MPEP 806-05 (h) provides for restricting out claims 12--37, as they demonstrate more than one use for the compounds.

Should claim 1 become allowable, applicants may elect one believable, supportable, method of use, of the same scope, to be examined therewith.

Assay tests or laboratory screen test are not acceptable.

A Broad statement of utility, as in the cited claims cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

The U.S.P.T.O. has amended the guidelines to clarify "specific utility.". The focus was on Brenner v. Manson. The utility need be one in the real World of commerce.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by the American Medical Association Council on Pharmacy, were alleged in the specification. Ex parte Timmis, (POBA 1959) 123 USPQ 581. Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating seven types of cancer with a member of a class of several compounds. In re Buting, (CCPA 1969) 418 F2d 540, 163 USPQ 689.

This method of claim 12 does not meet the real World of Commerce requirement.

Inhibiting IKK-2 is a laboratory screen test that does not meet the Utility Guidelines, of Brenner vs. Manson, cited below. This screen test for IKK-2 inhibition does set forth a specific disease in the real world of Commerce.

Claims 14, 16, 19, 28, 29, 30, 31, 32, 33, 36, 37 many diseases in a vague manner that are notoriously difficult to treat; that would require considerable proof, and not limited to one.

The agreement to examine one method of use with the elected compounds is based on their being of the same scope. Claims 23, 25, 26, 27, 34, 35 have additional active ingredients, therefore, they are not of the some scope as the compounds here. The additional search would be burdensome. Claims 23, 25, 26, 27, 34 and 35 would have to be restricted out here. Applicants

are entitled to the protection of 35 U.S.C. 121 in regard to the subject matter of claims 23, 24, 26, 27, 34 and 35; which could be the subject of a divisional application.

The additional active ingredient would likely control classification away from pyridine in class 514.

Restriction is proper where the compounds as claimed may be used for more than one purpose, the claims become evidence claims to that allegation.

The use needs to be believable, that applicants pick.

The Supreme Court declined to express a view as to whether patentability can be based on a product show to inhibit the growth of tumors in laboratory animals. Brenner, Comr. Pats. vs. Manson, (USSC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility: consists of its potential role as an object of use-testing, reasoning the patent system is related to the world of Commerce rather than the realm of philosophy ibid., 148 USPQ at 696.

MPEP 806.05 (h) provides for restricting out the method and composition claims, altogether, if applicants do not elect one specific real world disease. This is consistent with 37 CFR 1.475 and PCT Rule 13.2.

JOHN M. FORD
PRIMARY EXAMINER
1624

John M. Ford:jmr

December 20, 2002